Docket No.: 0259-0411PUS1
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Maurizio Dalle CARBONARE et al.

Application No.: 10/019,387 | Confirmation No.: 6340

Filed: March 26, 2003 | Art Unit: 1612

For: USE OF HYALURONIC ACID DERIVATIVES FOR THE PREPARATION OF PHARMACEUTICAL COMPOSITIONS AND BIOMATERIALS FOR THE PREVENTION OF THE FORMATION AND URE OF CUTANEOUS SCARS | Examiner: S. Maewall

ABATANGELO DECLARATION - DECLARATION UNDER 37 CFR 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Giovanni Abatangelo, do hereby declare the following:

1. Attached is a copy of my *curriculum vitae*.

2. I am presently a Full Professor of Histology and Embryology at the University of Padova, Italy.

3. I have over 25 years of experience in research on tissue engineering by use of hyaluronic acid based biomaterials.

4. I am familiar with the above referenced patent application, as well as the development, usages and properties of hyaluronic acid derivatives and their uses, in particular to reducing normotrophic scarring.

5. I have read and understand the subject matter of the Office Action of September 04, 2008.

6. I am familiar with the Declaration of Anna Maria Zanellato executed on February 3, 2009, which discussed experimental reports and offered comments in support of the patentability of the instant invention, and which Declaration was submitted to the USPTO with an Amendment on February 3, 2009.

7. I offer the following comments as further explanation of the experimental results submitted with the Zanellato Declaration, and to respond to some questions I understand were raised by the Examiners during an interview on February 25, 2009.

8. Explanation of the test result graph in Attachment 2 – I understand the Examiners questioned the meaning of the results in the graph of Attachment 2 of the prior Zanellato Declaration, namely the graph of the results of the test for "Areas of scarring". I understand that the Examiners questioned why the areas of scarring for samples A and B are low at day 1, are then about equal to C and D on day 3, and then are again reduced at days 14 and 42.

8.1. The process of wound healing involves three major overlapping phases: lag phase (inflammation and cytokine release), proliferation phase (epithelial cells and fibroblasts migration and proliferation, connective tissue deposition and angiogenesis), and remodeling phase (with cell number decreases and collagen fiber organization). (See Exhibit 1)

8.2. During the initial healing phase encompassing the first three to four days after wounding, the process of wound healing is initiated by thrombogenic stimuli, and immune cells infiltrate the injury site where platelets release a variety of cytokines and growth factors. Therefore, during this phase, inflammatory components prevail.

8.3. The proliferative phase (10 and 14 days after wounding) results in regeneration of epidermis, neoangiogenesis and proliferation of fibroblasts with increased collagen synthesis and closure of the skin defect.

8.4. The final remodeling phase takes place over 6 months.

8.5. In my opinion, it is evident that the areas of scarring for samples A and B are about equal to C and D on day 3 because this is the time of lag phase where inflammatory components prevail over the proliferation phase and, therefore, new tissue is not yet made. On day 1, the lag phase is starting and one can value an initial effect of the samples according to the invention. Nevertheless, on day 3 the lag phase is to maximum expression and the inflammation prevails over the samples' effects. Only in the proliferation phase (on day 14), can one estimate the real effect of the samples A and B according to the present invention.

9. Explanation of test results in Attachment 1 – I also understand that the Examiners requested some further explanation of the graph results in Attachment 1, namely the graph relating to "Effective hyaluronate formulations on wound coverage". Indication in the graph of the "wound coverage" is based on a score related to the length of epidermal coverage as a measure of "re-epithelialization". Thus, an increased number for "wound coverage" represents an increased amount of re-epithelialization, which is a positive result. The graph shows that tests D and E according to the present invention exhibited increased wound coverage (namely improved re-epithelialization); whereas, the comparative tests A, B and C showed wound coverage values either about the same as control or actually less than control.

In addition, I understand that the data presented below in Table 1 where provided in a newly submitted Zanellato Declaration 2, which the quantitative of values of improvement for the tested samples are provided, wherein samples D and E according to the present invention were

compared to the other samples, and wherein it is assumed that the value of wound coverage obtained with the control "alginate vehicle" is 100.

Table 1:

A	B	C	D	E	F
100	110	101	140	138	110

From these results it can be seen that samples D and E according to the present invention exhibited an improvement of about 40% in the wound coverage versus all control samples.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: March 9th, 2009

By _____
Giovanni Abatangelo

Prof. Abatangelo
Dept. Histology, Microbiology and Biomedical Techology
University od Pdova, Italy

Full Frofessor of Histology and Embriology, University of Padova, Italy.

Graduated as MD (University of Padua, 1965), Postodctoral Specialization in Clinical Pathology (University of Padua, 1977), Postdoctoral Fellow Dept. of Biochemistry, Baylor University of Baylor, Houston, Texas, Usa, (1965-1967), Lecturer, Institute of Histology, University of Padua (1970), Full Professor of Histology - Embriology, University of Padua (1975 - present).
President of the Italian Society of Cutaneous Biology and Member of the Editorial Board of "Wound Repair and Regeneration" (Mosby Inc., St. Louis MO, USA).

Organizer and President of the following Symposia:
- 1° and 2° International Symposium on Cutaneous Development , Aging and Repair, Padua, Oct. 4-7 1987 and Oct. 13-16 1991.
- 5° Annual Meeting of the European Tissue Repair Society.

President of the Consortium "TissueTech", a non-profit joint collaborative effort between the University of Padua and Biotechnological Industries dedicated to research project in biomaterials and tissue engineering for clinical use supported by the Italian Government, art. 10, L. 46/82(1989-2001).
Coordinator of research programs that obtained grants from Italian Ministry of University and Research (60%) and Italian National Council Research for the research project "Biomaterials in Orthopedics: Scaffolds for Bioengineered Cartilage".
Research Leader of Four-Year Grant from the European Community (Number QLK3-CT-1999-00625) entitled "Peripheral Nerve Repair"
Author and co-author of 60 papers on peer reviewed journals. During the last decade the interest is mainly devoted to tissue engineering of skin, cartilage and guided regeneration of small arteries.

Prof. Abatangelo research activities have focused for many years on tissue engineering by means hyaluronic acid-derived biomaterials as scaffold for the creation of in vitro artificial tissue such as: skin, cartilage, bone. "Smart scaffold" biomaterials are comprised of hyaluronan derivatives, namely the benzyl ester of this extracellular polysaccharide. All these scaffolds are highly biocompatible and when placed inside the human body, do not elicit any adverse reactions and are resorbed by the host tissues. Abatangelo's laboratories have cultured different kinds of cellular types:

- human dermal fibroblasts: able to attach to the biomaterial fibers, proliferate, colonize the entire device, and secreted the main extracellular molecules (collagen type I, III and IV, laminin, fibronectin) giving rise to a dermal-like tissue;
- keratinocytes able to give rise a complete skin equivalent when they are in vitro cultured onto this dermal substitute [Zacchi 1998; Galassi 2000; Tonello 2005],
- endothelial cells seeded into this in vitro reconstructed connective tissue are able to proliferate and organize themselves into microcapillary structures [Tonello 2003];
- chondrocytes were cultured inside non-woven Hyaff™ (Hyaluronic benzilic ester, FIDIA Abano Terme) scaffolds, are able to generate clusters of proliferating chondrogenic cells that produce type II collagen and proteoglycans were obtained (Brun 1999).
- Bone Marrow Mesenchimal Stem are able to differentiate to several mesenchymal tissues including: bone, cartilage, connective tissue (Radice, 2000).

The in vitro reconstructed dermal substitutes obtained by culturing the patient own fibroblasts into a 3D Hyaluronan based scaffolds, are routinely used in the clinical practice in many hospital (Galassi et al 2000; Brun et al. 2000)for the treatment of skin lesion. Also autologous human chondrocytes cultured into the above described scaffolds are being used for the treatment of cartilage lesion.

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